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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,507	09/28/2006	Haruo Sugiyama	296846US0PCT	1680
22850	7590	09/29/2008	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	
			NOTIFICATION DATE	DELIVERY MODE
			09/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/594,507	Applicant(s) SUGIYAMA, HARUO	
	Examiner Jeffrey E. Russel	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 4-10 and 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20070328;20071102</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1654

1. Applicant's election without traverse of the invention of Group I, claims 1-3 and 11-13, and the species peptide of SEQ ID NO:9 in the reply filed on August 4, 2008 is acknowledged.

Claims 4-10 and 14-20 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on August 4, 2008.

2. The Sequence Listing filed May 29, 2007 is approved.

3. The abstract of the disclosure is objected to because of the presence of the legal terminology "said". Correction is required. See MPEP § 608.01(b).

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

See page 30, line 5.

5. The disclosure is objected to because of the following informalities: At page 7, line 25, "binding" is misspelled. At page 37, line 28, "very" should be changed to "every". Appropriate correction is required.

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims read on a product of nature, i.e. intact human WT1. A product of nature does not constitute patentable subject matter. Note the claims do not require, e.g., a purified or isolated product. Note also that Applicant's specification at page 9, line 3, states that there are no limitations as to the lengths of the peptides of the invention. With respect

Art Unit: 1654

to instant claim 3, note that intact human WT1 will comprise each of the three fragments recited in instant claim 2, i.e. will comprise multiple epitopes capable of inducing CTLs, and therefore naturally-occurring human WT1 also constitutes an epitope peptide. See page 10, line 25 - page 11, line 15, for Applicant's description of epitope peptides.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 00/26249. The WO Patent Application '249 teaches peptide fragments of WT1, RMFPNAPYL and CMTWNQMNL, and teaches pharmaceutical compositions comprising the peptides. The peptides can elicit production of CTLs and are useful as cancer vaccines. See, e.g., the Abstract; page 8, lines 6-8; and claims 1-5, 15, and 19. In view of the similarity in source, amino acid sequence, and utility between the peptides of the WO Patent Application '249 and Applicant's claimed peptides, the peptides of the WO Patent Application '249 are deemed inherently to have activity as an HLA-A26-binding cancer antigen peptide to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptides of the WO Patent Application '249 and Applicant's claimed peptides to shift the burden to Applicant to provide evidence that the claimed peptides are unobviously different than the peptides of the WO Patent Application '249.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by the Sugiyama article (Int. J. Hematol., Vol. 76, pages 127-132). The Sugiyama article teaches the peptide

Art Unit: 1654

SLGEQQYSV (see page 129, column 2, first full paragraph), which is a fragment corresponding to residues 187-195 of human WT1. In view of the similarity in amino acid sequence between the peptide of the Sugiyama article and human WT1 and Applicant's peptide having SEQ ID NO:9, the peptide of the Sugiyama article is deemed inherently to have activity as an HLA-A26-binding cancer antigen peptide to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the peptide of the Sugiyama article and Applicant's claimed peptides to shift the burden to Applicant to provide evidence that the claimed peptides are unobviously different than the peptide of the Sugiyama article.

10. Claims 1-3 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 03/037060. The WO Patent Application '060 teaches peptides identified as SEQ ID NOS:244, 60, and 166 (see pages 94, 98, and 118) which are the same as Applicant's peptides identified as SEQ ID NOS:8, 2, and 9, respectively. The WO Patent Application '060 also teaches a vaccination composition comprising an immunogenic fragment of WT-1 corresponding to residues 2-281. See page 175, lines 4-6, and Example 35 in general. The amino acid sequence of this fragment is taught at page 173, lines 27-29 (identified as SEQ ID NO:461), and comprises Applicant's SEQ ID NO:8 and SEQ ID NO:9 (see positions 151-159 and 184-192 of SEQ ID NO:461). Because the fragment of the WO Patent Application '060 comprises multiple epitopes capable of inducing CTLs, the fragment also constitutes an epitope peptide. See page 10, line 25 - page 11, line 15, for Applicant's description of epitope peptides. See also Figure 18 of the WO Patent Application '060, for teachings of additional proteins which anticipate Applicants' claims. In view of the similarity in source, amino acid sequence, and utility between the fragment of the WO Patent Application '060 and Applicant's claimed

Art Unit: 1654

peptides, the fragment of the WO Patent Application '060 is deemed inherently to have activity as an HLA-A26-binding cancer antigen peptide to the same extent claimed by Applicant.

Sufficient evidence of similarity is deemed to be present between the fragment of the WO Patent Application '060 and Applicant's claimed peptides to shift the burden to Applicant to provide evidence that the claimed peptides are unobviously different than the fragment of the WO Patent Application '060. With respect to instant claims 12 and 13, note that intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

11. Claims 1-3 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaiger et al (U.S. Patent Application Publication 2003/0082194). Gaiger et al teach a peptide identified as SEQ ID NO:166, which is identical to Applicant's peptide identified as SEQ ID NO:9. Gaiger et al also teach that plural copies of the peptide can be joined to form a single peptide. Gaiger et al teach that the peptide can be combined with a pharmaceutical excipient and can be used to elicit T cell response and to formulate vaccines. See, e.g., the Abstract; paragraphs [0015], [0183], and [0184]; Tables 26 and 34; and claims 1 and 31. Gaiger et al's peptide comprising plural copies of the peptide identified as SEQ ID NO:166 corresponds to Applicant's epitope peptide. See page 10, line 25 - page 11, line 15, for Applicant's description of epitope peptides.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
September 25, 2008